

### **REMARKS**

Reconsideration of this application is respectfully requested. Claim 62 has been amended to specify that the pharmaceutical composition includes at least one active agent selected from calcitonin, human growth hormones, recombinant human growth hormones, parathyroid hormone, and fragments of parathyroid hormone. Claim 64 has been canceled without prejudice. Claims 67-70 have been added. Support for these amendments is found at, for example, page 7, lines 15-32, and page 8, line 23, of the specification. Claims 29, 62, 63, and 65-70 are pending and at issue.

### **Obviousness Rejections**

Claims 29 and 62-66 stand rejected under 35 U.S.C. §103(a) as obvious over International Publication No. WO 96/30036 in view of International Publication No. WO 97/36480, U.S. Patent No. 5,773,647 (the '647 Patent), International Publication No. WO 95/28838, and U.S. Patent No. 4,757,066.

Applicants respectfully traverse this rejection and request reconsideration.

The Examiner argues that the recitation in the claims that the pharmaceutical composition comprises at least about 50% by weight of a disodium salt of *N*-(5-chlorosalicyloyl)-8-aminocaprylic acid (5-CNAC) does not “bear any patentable weight as the reference may inherently have that limitation ...” (underlining added, page 3 of the December 5, 2006 Office Action). However, inherency cannot be based on a result which may occur, rather the result must “necessarily flow” from the teachings of the prior art reference. *See Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). As explained at MPEP 2112.IV:

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of

conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted) ... Also, "[a]n invitation to investigate is not an inherent disclosure" where a prior art reference "discloses no more than a broad genus of potential applications of its discoveries." *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1367, 71 USPQ2d 1081, 1091 (Fed. Cir. 2004) (explaining that "[a] prior art reference that discloses a genus still does not inherently disclose all species within that broad category" but must be examined to see if a disclosure of the claimed species has been made or whether the prior art reference merely invites further experimentation to find the species[]).

The Examiner further argues that because the patent "specifically say [sic] salts .... With 2-hydroxy groups it is obvious it [i.e., 5-CNAC] would form a disodium salt." (Page 3 of the December 5, 2007 Office Action). However, a skilled artisan would recognize that 5-CNAC can form a monosodium salt (e.g., a sodium salt at the carboxy terminus of the 5-CNAC compound). Accordingly, it does not necessarily follow that when a sodium salt of 5-CNAC is formed, it would necessarily be a di-sodium salt. Therefore, the '647 Patent does not inherently disclose a pharmaceutical composition comprising at least about 50% by weight of a disodium salt of 5-CNAC as recited in the claims.

Furthermore, the '647 Patent and the other cited references do not disclose or suggest the benefits of the disodium salt over the corresponding monosodium salt. In particular, the disodium salt provides superior delivery of active agents. In Example 4 of the present application, 400 mg of disodium 5-CNAC or monosodium 5-CNAC was orally administered to monkeys with salmon calcitonin. The mean peak plasma concentration resulting from the disodium salt dose was over four times that of the monosodium salt dose. The area under the curve (AUC) for the disodium salt dose was over five times that of the monosodium salt dose. See Table 1 on page 15 of the specification. These benefits are not suggested in the cited references.

Accordingly, the cited references alone or in combination do not render obvious the presently claimed invention and applicants respectfully request withdrawal of this rejection.

Claims 29 and 62-66 have also been rejected under 35 U.S.C. §103(a) as obvious over the '647 Patent.

Applicants respectfully traverse this rejection and request reconsideration.

As discussed above, the '647 Patent does not inherently disclose a pharmaceutical composition comprising at least about 50% by weight of the disodium salt of 5-CNAC.

The Examiner argues at page 5 of the December 5, 2006 Office Action that the '647 Patent discloses an injectable solution in which the pH of the solution is adjusted to a pH of 7.2 to 8, citing page 46 of the patent. The '647 Patent, however, does not disclose such an injectable solution. The Examiner appears to be referring to page 46 of an unrelated application, WO 96/30036 (WO '036). As this rejection is said to be based solely on the '647 Patent, the disclosure of WO '036 is not relied upon for the rejection.

For foregoing reasons, the '647 Patent does not render obvious the presently claimed invention and applicants respectfully request withdrawal of this rejection.

### **Written Description Rejections**

Claims 29 and 62-66 stand rejected for failing to comply with the written description requirement. The Examiner contends that, while claims 62-66 are not limited to any specific active agent, there is no written description that all active agents have "pharmaceutical" activity. The Examiner also argues that there is no written description of what "vitamins, growth hormones, interferons, human recombinant insulin, analogs, fragments and so on" are, stating that the description does not provide a partial structure of what is encompassed by these groups. The

Examiner further contends that “analogs”, fragments[,] mimetics, [and] derivatives” could be any chemical compound.

While applicants respectfully disagree with the Examiner, in order to expedite prosecution, claim 62 has been amended to specify that the active agent is selected from calcitonin, human growth hormones, recombinant human growth hormones, parathyroid hormone, and fragments of parathyroid hormone. Applicants respectfully submit that one of ordinary skill in the art would readily understand what is meant by each of these terms, as they refer to well known active agents and classes of active agents. *See*, for example, claim 10 of U.S. Patent No. 7,163,698 (“calcitonin” and “parathyroid hormone”), claim 27 of U.S. Patent No. 7,138,105 (“human growth hormone”), claim 1 of U.S. Patent No. 6,869,600 (“recombinant human growth hormone”); and claim 32 of U.S. Patent No. 6,998,423 (“active fragments of parathyroid hormone”).

For the foregoing reasons, applicants respectfully request withdrawal of this rejection.

In view of the above amendments and remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue.

If there are any other issues remaining, which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

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Respectfully submitted,

By /Jay P. Lessler/  
Jay P. Lessler  
Registration No.: 41,151  
DARBY & DARBY P.C.  
P.O. Box 5257  
New York, New York 10150-5257  
(212) 527-7700  
(212) 753-6237 (Fax)  
Attorneys/Agents For Applicant